

External Quality Control Log Instructions

Use this external quality control (EQC) log to document the process each time external controls are run. External controls should be run periodically and after certain triggering events to establish that the OraQuick test kits are functioning properly. See the OA rapid testing guidance for more information.

This log consists of two sides or pages. The “front” side is labeled “External Quality Control Log for (month)/(year).” The “back” side is for problem documentation related to EQC procedures.

Front Side

To run EQC, two tests kits are used. One test kit is used to process the negative sample, and one to process the positive sample. The information and outcome for both tests are recorded across a single line of the EQC log.

Date

Date the controls are run

Site

Identifying code for the site at which these controls are run. Should be consistent with information used in HIV Counseling Information System.

Initials

Initials or numeric code of counselor or technician conducting controls. Should be consistent with information entered into HIV Counseling Information System.

QC code

Reason or triggering event for running controls. See codes listed on bottom of front side.

Test kit – Lot #

Lot number listed on outside pouch of the test kits used. Both test kits must have the same lot number and expiration date. If testing more than one lot, run a positive and negative control for each lot.

Test kit – Exp date

Expiration date listed on outside pouch of the test kits used.

Control Kit – Lot #

The lot number listed on the outside of the control unit box.

Control Kit – Closed vial exp

The expiration date printed by the manufacturer on the outside of the control unit box.

Control Kit – Open vial exp

Control units expire after a specified period of time has passed since opening. (See control unit package insert for time period specified by manufacturer. As of this writing [Sep 03], the package insert indicates that control units expire three weeks after opening.) Both the date the vials were opened and the date the controls expire must be handwritten on the control unit box when opened.

Negative (Positive) Control – Start time/temp

The time and temperature in the testing area when the test kit processing the negative (positive) control was inserted into the vial of reagent.

Negative (Positive) Control – End time/temp

The time and temperature in the testing area when the test kit processing the negative (positive) control was read; must be within the time period specified by the manufacturer.

Negative (Positive) Control – Result

Circle “P” if the result was positive or reactive; N if the result was negative or non-reactive; or “I” if an invalid result was obtained.

Result Acceptable?

Circle “Yes” if the positive control yielded a positive result and the negative control yielded a negative result. For any other combination of results, including invalid, circle “No.” If the result of the EQC process is unacceptable, document the problem on the back of the EQC log and take proper steps to remedy the problem, according to OA guidelines and site-specific QA procedures. Client testing using the OraQuick device must be halted until the problem can be resolved and proper functioning of the test kits is verified.

Back Side

Entries should be made on the back side of the EQC log in two general cases:

1. If controls are required for an unusual reason
2. If controls fail

If controls are required for an unusual reason

If it is necessary to run controls for a reason not listed on the front of the log under “QC code,” document the reason for running controls on the backside of the log.

Some possible reasons could be: two invalid test results in a row, an unusual number of positive results given local prevalence, or any other event that calls into question the functioning of the test kits.

If this occurs, document the date of the event, the Unique OA Number(s) from the CIF if the event is related to a specific client test, the initials of the technician running the controls, the lot number and expiration date of the test kit, the problem, and the corrective action taken.

If controls fail

If controls being run for any reason fail, document this event on the back of the EQC log. Include the date, [skip the box labeled “CIF”], the initials of the technician running the controls, the lot number and expiration date of the test kit, the problem, and the corrective action taken.

Under “problem,” list “failed controls” along with an explanation, if known. (For instance, controls may fail because the technician neglected to insert the sample, or the test kit was knocked over while in process. If this is known to be the case, document that here.)

Under “corrective action taken,” document what steps were taken to resolve the problem, such as re-running controls, re-running controls with a new control unit, notifying the manufacturer, etc.